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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,625	12/21/2001	Sabine Stumvoll	25401-5	1495

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EXAMINER
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ROONEY, NORA MAUREEN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/027,625

**Applicant(s)**

STUMVOLL ET AL.

**Examiner**

Nora M. Rooney

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 08/24/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-21 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-21 and 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 9-21 and 23-29 are pending.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 9-21, 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrases: "in an individual known to be allergic" claimed in claim 9; and "in an individual known to be allergic, from among a variety of possible allergen sources" claimed in claim 23 represent a departure from the specification and the claims as originally filed.

**Applicant's amendment does not point to the specification for support for the newly added claim limitations. In particular, the amendment does not provide support for the limitations "in an individual known to be allergic" claimed in Claim 9 and "in an individual known to be allergic, from among a variety of possible allergen sources" claimed in Claim 23. The specification and the claims as originally filed do not provide a clear support for these claim limitations.**

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 9-21 and 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Duro et al. (ad on the IDS submitted 7-1-02), for reasons of record set forth in the Office Action mailed 2-25-05.

Applicant's arguments filed 08-24-2006 have been fully considered but are not found persuasive

Applicant argues that claims 9-21 and 23-29 are not anticipated by and are patentably distinguishable from the teachings of Duro et al. Applicant argues on page 8 of the reply filed on 08-24-2006 that "the present methods are for accurately identifying the actual sensitizing allergen source (for example, the actual sensitizing pollen) from among a variety of allergen sources (for example, various weed pollens) for an individual who is already known to be allergic." Applicant goes on to say that "the present methods are for identifying to which particular allergen source, for example, to which pollen, the individual is allergic.." and "not for generally diagnosing allergy." Applicant argues that Duro et al. fails to teach a method for serologically identifying the actual sensitizing allergen source among a variety of possible allergen sources because Duro et al. is directed to a single allergen source. Applicant further argues that claims 9, 23 and 26 recite the additional steps determining the presence of IgE binding to the pure allergen component in the serum and, if the serum contains IgE binding to the pure allergen component, identifying the allergen source from which the pure allergen component is derived as the actual sensitizing allergen source. Lastly, applicant argues that Duro et al., do not teach a method for selection of an allergy treatment involving extract, proteins or peptides derived from said allergic sensitizer.

Duro et al., teaches contacting serum with recombinant Par j 2 to detect pollen allergy. Duro et al., further teaches that the characterization of the recombinant antigen

is a preliminary step for use of said protein therapeutically. The prior art teaches all of the method steps of the claimed invention and as such anticipates the claimed invention. The preamble adds no additional limitations to the claims since the same product was used in the same method steps for identifying allergens from patients.

Duro et al., does teach serologically (from serum) identifying the actual sensitizing allergen (recombinant Par j2) from a variety of possible allergen sources, since the patients were Parieta judaica pollen sensitive and since Duro teaches there are nine possible allergens in P. judaica pollen and 82% of the P. judaica pollen sensitive patients serums' IgE reacted with recombinant Par j2. Additionally, Duro et al. inherently teaches serologically identifying the actual sensitizing allergen (recombinant Par j2) from a variety of allergen sources since Par j2 is the allergen selected amongst all allergens to perform the experiments. It is also noted that amongst the Parieta judaica allergic patients' serum that were tested, the IgE of only 82% of patients reacted with Par j2. If the Par j2 is a pure allergen component without cross-reactivity with use as a diagnostic tool for diagnosing that specific allergy, then this information shows that 18% of the patients were not allergic to P. judaica. Therefore, the results inherently show that 18% of the patients were allergic to another allergen from a variety of allergen sources other than P. judaica, presumably with cross-reacting proteins or epitopes to P. judaica.

In addition, Duro et al., does teach that previous to their disclosed method that the P. judaica allergen was known to have at least 9 allergens having different molecular weights and in order to plan a diagnostic and therapeutic approach to allergic reaction a preliminary step is to purify and characterize (i.e. serologically identify with improved accuracy) each major allergen by cloning the allergen and testing its immunoreactivity in blood from patients with P. judaica reactivity. This method anticipates the method according to claim 10 that recites the selection of the allergy treatment involves extract, protein or peptides derived from the allergen source. The

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preliminary steps above include peptides and proteins and are necessary to plan a diagnostic and therapeutic approach as taught by Duro et al.

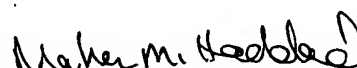
6. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 2, 2006

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MAHER M. HADDAD  
PRIMARY EXAMINER